

## REMARKS

### I. Second Request for Consideration of A Previously Submitted Information Disclosure Statement

An Information Disclosure Statement and four cited references were submitted to the U.S. Patent and Trademark Office on October 20, 1999 when this patent application was originally filed. However, an initialed PTO Form-1449, indicating review of these references was not received.

Subsequently, a request for review of that Information Disclosure Statement was made in Applicants' response filed January 15, 2002. Yet to Applicants' knowledge, review of this Information Disclosure Statement has not yet occurred.

Applicants also note that the Japanese Abstract JP 09-071523-A, (A2 on the form) was subsequently reviewed when submitted as part of a different Information Disclosure Statement, as the Examiner signed off on this reference on January 29, 2002. However, the other three references still await consideration.

Therefore, a second request for the Examiner's consideration of the Information Disclosure Statement is made.

### II. Discussion of the Rejection under 35 U.S.C. Sec. 103(a) over Shimizu *et al.*

Claims 20, 21, 23-26 and 28-32 have been rejected under 35 U.S.C. Sec. 103(a) as unpatentable over Shimizu *et al.*, U.S. Patent No. 6,299,904. Applicants respectfully traverse the rejection as the cited reference is not proper art.

Applicants respectfully draw the Examiner's attention to related U.S. Patent Application Serial No. 09/800,839. This case was also being handled by the Examiner, and the same '904 reference was asserted as art by her.

The most recent communication from the U.S. Patent and Trademark Office for the related case was an Advisory Action dated July 14, 2003 from Supervisory Examiner Thurman Page. This Advisory Action apparently withdraws the rejection over the '904 reference which had been imposed by Examiner Tran. Apparently, Supervisory Examiner Page has agreed with the Applicants' position that the '904 reference is not proper art.

The Examiner has stated that she relies upon the date of the Japanese priority document of 5/27/97 to make the '904 reference proper art. Use of this date is not allowed under the law. She believes that if she has the document, which is in Japanese, translated, she may rely upon that date. This makes no sense whatsoever. If the priority document is not in English, its filing date cannot be used to ante-date the related cited U.S. patent.

The Examiner is respectfully requested to discuss the appropriateness of the citation of the '904 patent as art with Supervisory Examiner Page before asserting the '904 reference improperly yet again.

For the reason provided above, Applicants respectfully request reconsideration and withdrawal of the 35 U.S.C. Sec. 103(a) rejection over Shimizu *et al.*

III. Discussion of the Rejection under 35 U.S.C. Sec. 103(a) over Ohno *et al.* in view of Shimizu *et al.*

Claims 21, 21, 23-26 and 28-32 have been rejected under 35 U.S.C. Sec. 103(a) as unpatentable over Ohno *et al.*, U.S. Patent No. 5,958,453 in view of Shimizu *et al.*, U.S. Patent No. 6,299,904. Applicants respectfully traverse the rejection.

As stated in Sec. II above, Applicants do not believe the '904 patent is citable against them, in view of the priority of their application. Since the '904 reference is not proper art, the teachings of the '904 reference cannot be combined with the teachings of the '453 reference to obtain the aspects of the invention set forth in the pending claims.

Therefore, Applicants respectfully request withdrawal of the 35 U.S.C. Sec. 103(a) over Ohno *et al.* in view of Shimizu *et al.*

IV. Discussion of the Rejection under 35 U.S.C. Sec. 103(a) over Ohno *et al.* in view of Shashoua *et al.*

Claims 20, 21, 23-26 and 28-32 have been rejected under 35 U.S.C. Sec. 103(a) as obvious over the Ohno *et al.*, U.S. Patent No. 5,958,453 in view of Shashoua *et al.*, U.S. Patent No. 5,795,909. Applicants respectfully traverse the rejection, as one skilled in the art of

pharmaceutical formulation would not have been motivated to combine the teachings of the two cited references.

The '909 reference is directed to conjugates useful for treating cell proliferative disorders, wherein an active agent is combined with another chemical compound, according to the Abstract.

In the Summary, at col. 3 of the cited reference, it is further stated that "[t]he present invention involves the unexpected finding that conjugates of pharmaceutical agents and a highly lipophilic group, a C22 unbranched carbon chain, have a different selectivity relative to the unconjugated pharmaceutical agents."

More specifically, in the '909 reference, active agents are conjugated to another compound, cis-docosahexanoic acid, to improve the odds that the active agent will reach a target tissue. A laundry list of pharmaceutical ingredients which is twenty six columns long follows a statement in the reference at column 19 that DHA may be conjugated to virtually any drug compound. The list of active agents which may be conjugated according to the teaching of the '909 reference includes lansoprazole.

The Examiner has stated that "it would have been obvious for one of ordinary skill in the art to modify Ohno's formulation using lansoprazole as an active agent in view of the teachings of Shashoua." In making this statement, the Examiner has appropriated the lansoprazole; while choosing to leave the concept of conjugation of active agent (such as lansoprazole) behind.

The Examiner has ignored the principle that the cited art should be considered in its entirety. It has been stated that "[i]t is impermissible within the framework of section 103 to pick and choose from any one reference only so much of it as will support a given position, to the exclusion of other parts necessary to the full appreciation of what such reference fairly suggests to one of ordinary skill in the art" in *In re Wesslau*, 353 F.2d 238, 241. This statement characterizes what the Examiner has done in this instance to shrink the '909 reference such that it appears to disclose the only the content that the Examiner desires it to cover.

A formulation chemist desiring to create an improved formulation of lansoprazole, and in possession of the teachings of the '453 reference would not have been motivated to combine with that reference the teachings of the Shashoua *et al.* conjugates to obtain the invention set forth in the pending claims.

So Applicants assert that although the Examiner's reason for combining the two references appears logical to the Examiner on paper, those skilled in the art would not have seen or made any connection whatsoever between the two references.

Therefore, Applicants continue to assert that the two references would not have been combined by those skilled in the art; and moreover that the Examiner has merely gleaned a word or two from a reference without considering the teaching as a whole prior to making a broad characterization of the reference.

Therefore, Applicants respectfully request withdrawal of the rejection under 35 U.S.C. Sec. 103(a) over Ohno *et al.*, U.S. Patent No. 5,958,453 in view of Shashoua *et al.*, U.S. Patent No. 5,795,909.

V. Discussion of the Watanabe *et al.* Reference

Applicants wish to that the Examiner for bringing the Watanabe *et al.* reference to their attention. Applicants have carefully reviewed this reference, and do not believe that it detracts from the patentability of the subject invention.

VI. Conclusion

Reconsideration of the claims in view of the arguments made above is solicited. Should the Examiner believe that a conference with Applicants' attorney would advance prosecution of this application, she is respectfully requested to call Applicants' attorney.

Respectfully submitted,

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Elaine M Ramesh

(847) 383-3391  
(847) 383-3372

Elaine M. Ramesh, Ph.D., Reg. No. 43,032  
Mark Chao, Ph.D., Reg. No. 37,293

Attorney for Applicants  
Customer No. 23,115

Takeda Pharmaceuticals North America, Inc.  
Intellectual Property Department  
Suite 500, 475 Half Day Road  
Lincolnshire, IL 60069 USA

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Gail L. Winokur

Printed Name: Gail L. Winokur